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12M2/0617

ANDRUS SCALES STARKE AND SAWALL  
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MILWAUKEE WI 53202

**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

☐ Note attached communication from the Examiner

☐ This notice is issued in view of applicant's communication filed \_\_\_\_\_

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/502,288	07/13/95	011	SPIVACK, P	1205 06/17/96
First Named Applicant				

TITLE OF INVENTION: DELUCA, HECTOR F.  
PREVENTION OF HYPERPHOSPHATEMIA IN KIDNEY DISORDER PATIENTS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1256-00510	514-167.000	B10	UTILITY	NO	\$1250.00	09/17/96

**THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.  
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY Status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/502,288 07/13/95 DELUCA

H 1256-00510

EXAMINER  
SPIVACK, P

12M2/0617

ANDRUS SCEALES STARKE AND SAWALL  
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ART UNIT PAPER NUMBER

1205

9

DATE MAILED: 06/17/96

### NOTICE OF ALLOWABILITY

#### PART I.

1. ☒ This communication is responsive to Amendment filed April 2, 1996
2. ☒ All the claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☒ The allowed claims are 4, 5, 10-18, now renumbered 1 to 11
4. ☐ The drawings filed on \_\_\_\_\_ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received. ☐ not been received. ☐ been filed in parent application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_.
6. ☐ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☒ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☒ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

#### PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☒ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. \_\_\_\_\_. CORRECTION IS REQUIRED.
  - b. ☐ The proposed drawing correction filed on \_\_\_\_\_ has been approved by the examiner. CORRECTION IS REQUIRED.
  - c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - d. ☒ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

#### Attachments:

- |  |  |
|--|--|
| <input type="checkbox"/> Examiner's Amendment                        | <input type="checkbox"/> Notice of Informal Application, PTO-152 |
| <input type="checkbox"/> Examiner Interview Summary Record, PTOL-413 | <input type="checkbox"/> Notice re Patent Drawings, PTO-948      |
| <input checked="" type="checkbox"/> Reasons for Allowance            | <input type="checkbox"/> Listing of Bonded Draftsmen             |
| <input type="checkbox"/> Notice of References Cited, PTO-892         | <input type="checkbox"/> Other                                   |
| <input type="checkbox"/> Information Disclosure Citation, PTO-1449   |  |

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1. The following is an Examiner's Statement of Reasons for Allowance: Applicants' Amendment filed April 2, 1996, Paper No. 7, is acknowledged. Claims 1 to 3 and 6 to 9 are canceled. New claim 18 is presented. Claims 4, 5 and 10 to 18 are presently under consideration.

Subsequent to the cancellation of claim 1 and the introduction of claim 18, the claims are limited to the method of treating a kidney disorder that is renal osteodystrophy. Accordingly, the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn because this issue of enablement is rendered moot.

The disclosure was objected to under 35 U.S.C. 112, first paragraph, in the last Office Action as failing to provide an enabling disclosure. It was asserted undue experimentation would be required by one skilled in the art to determine which vitamin D compound exhibits the desired effect of suppressing hyperparathyroidism while at the same time having a minimal effect on calcium and phosphorus levels. New claim 18 is limited to 19-nor-vitamin D<sub>2</sub> type compounds. Accordingly, the objection of record is withdrawn.

Claims 1, 4 to 7 and 14 to 17 were rejected in the last Office Action as being unpatentable over both Lee et al., Proc. Workshop Vitam. D, and DeLuca et al., U.S. Patent No. 5,246,926. The instant claims are directed to methods of administering 19-

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nor vitamin D<sub>2</sub> compounds where there is renal failure, which is in contradistinction to Lee's teaching where there is normal renal function. Further, Lee teaches a normalizing effect of 1,25-dihydroxyvitamin D<sub>3</sub> that may lead to an increase or decrease in levels of phosphorus. The instant methods result in no change in serum phosphorus levels. DeLuca does not teach or suggest an effect on phosphorus levels and the clear use of 19-nor vitamin D<sub>2</sub> to treat renal osteodystrophy. Thus the rejection of record under 35 U.S.C. 103 is withdrawn.

There is no teaching or suggestion in the references of the prior art to motivate one of ordinary skill in the art to modify prior methodologies involving the administration of vitamin D compounds and expect to arrive at the present method of treating renal osteodystrophy while avoiding hyperphosphatemia through administration of a 19-nor vitamin D<sub>2</sub> compound. Claims 4, 5 and 10 to 18 are allowed in view of the contemporary knowledge of the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Serial Number: 08/502288

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2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Spivack whose telephone number is (703) 308 4703.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308 1235.

Phyllis G. Spivack  
12 June 1996

*Phyllis Spivack*

**PHYLLIS SPIVACK  
PATENT EXAMINER  
GROUP 120**